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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/820,346

04/07/2004

Vilambi NRK Reddy

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8167

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K&L GATES LLP
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EXAMINER

MENDEZ, MANUEL A

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

11/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/820,346	Applicant(s) REDDY ET AL.	
	Examiner Manuel A. Mendez	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04/03/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In line 14, the claim discloses “at least one of the following” followed by an alphabetical listing of structural limitations. However, limitation (a), discloses the phrase “an insulating dielectric coating positioned adjacent to at least a portion of at”. Limitation (a) appears to be incomplete sentence. Correction is respectfully requested.

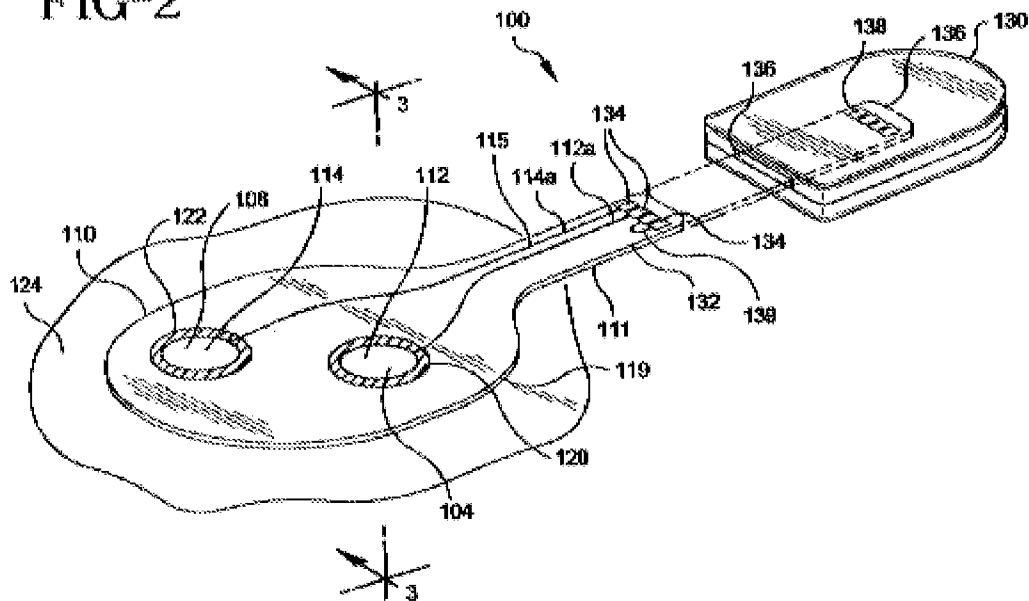
Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

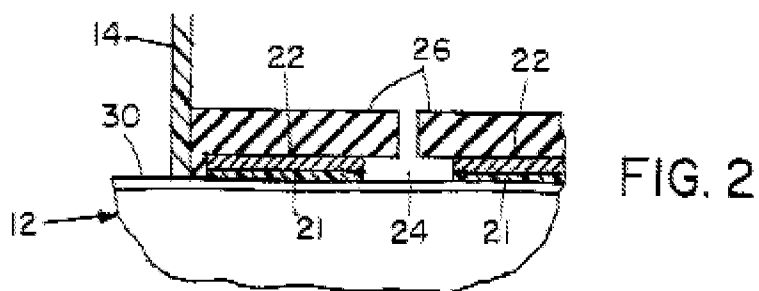
Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Keusch et al.** (US 6,635,045; hereafter **Keusch**) in view of **Weaver et al.** (US 5,911,223; hereafter **Weaver**), **Haak et al.** (US 5,158,537; hereafter **Haak**) or **Petelenz et al.** (US 4,752,285; hereafter **Petelenz**).

FIG-2



The Keusch patent shows in figure 2, a flexible backing; an electrode layer connected to said flexible backing, said electrode layer having at least a donor electrode and a return electrode; at least one lead extending from each of said donor electrode and said return electrode to a tab end portion of said assembly, said tab end portion being structured for electrical connection with at least one component of said electrically assisted delivery device; a donor reservoir positioned in communication with said donor electrode, said donor reservoir including an amount of said composition; a return reservoir positioned in communication with said return electrode.

The Keusch patent does not disclose an insulating dielectric coating positioned adjacent to at least a portion of at least one of electrodes. However, the use of dielectric coating in infusion devices is well known in the art as evidenced by the teachings of Weaver.



The Weaver patent shows in figure 2, a dielectric coating (21). Moreover, in column 6, lines 19-22, the specification states that “suitable materials for an electrically Insulating dielectric coating 21 include Teflon, Mylar, etc. and oxides such as aluminum oxide and tantalum oxide. Accordingly, based on the evidence at hand, the Weaver patent demonstrates the conventionality of using dielectric coatings in infusion devices.

In relation to **claims 2 and 3**, the Haak patent suggests that the infusion of compositions such as **epinephrine** and **lidocaine** is well known in the art. In column 13, lines 38-50, the specification states that “[t]he invention is particularly useful in the controlled delivery of peptides, polypeptides, proteins, macromolecules and other drugs which have a tendency to be unstable, hydrolyzed, oxidized, denatured or otherwise degraded in the presence of the liquid, such as water, necessary to conduct iontophoresis. For example, drugs containing either an ester bond (i.e., steroids) or an amide bond (i.e., peptides) may be hydrolyzed in water. Specific examples of drugs which can become degraded in the presence of water include catachols, such as apomorphine and **epinephrine**, salbutamol, sulfhydryls such as captopril, niphedipine, and peptides such as VIP and insulin”. Additionally, in column 1,

Art Unit: 3763

lines 35-52, the specification states that “[t]he iontophoresis process has been found to be useful in the transdermal administration of medicaments or drugs including **lidocaine** hydrochloride, hydrocortisone, fluoride, penicillin, dexamethasone sodium phosphate, insulin and many other drugs”. Finally, in relation to claim 4, in column 14, line 15, the Petelenz patent demonstrates that the use of **Ag/AgCl** electrodes is well known in the art.

Based on the above observations and comments, for a person of ordinary skill in the art, modifying the apparatus disclosed by Keusch with (1) an insulating dielectric coating, as taught by Weaver, (2) the infusion of epinephrine or lidocaine, as taught by Haak, and (3) the use of Ag and AgCl electrodes, as taught by Petelenz, would have been considered obvious in view of the proven conventionality in the art of these particular enhancements.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel A. Mendez whose telephone number is 571-272-4962. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Mr. Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3763

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Manuel A. Mendez/

Primary Examiner, Art Unit 3763

Manuel A. Mendez
Primary Examiner
Art Unit 3763